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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/536,982 | 05/31/2005 | Shlomo Lewkowicz | P-4433-US | 6340 |
| 49443 7590 05/08/2009 Pearl Cohen Zedek Latzer, LLP 1500 Broadway 12th Floor New York, NY 10036 | | | | |
| EXAMINER LAMPRECHT, JOEL | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,982

Applicant(s)

LEWKOWICZ ET AL.

Examiner

JOEL M. LAMPRECHT

Art Unit

3737

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-27, 29-31 and 35-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-27, 29-31 and 35-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S506)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **24-27, 29, 30, 31, 35-39, and 42-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Luiken (US 2001/0055566 A1) in view of Alfano et al (US 6,240,312 B1). Luiken discloses tumor screening related methods including administration of fluorescent dye and irradiation with visible and fluorescent (excitation) radiation to produce images captured on an image sensor (0004-0007) for the purpose of diagnosing cancerous tissues. The light excitations including both monochromatic light, polychromatic light, and combinations of flashing sequences (0009, 0018-0024), the incorporation of black-light or Woods lamps for dark periods of capture (0021), the

acquisition of real images and fluoroscopic images during different time periods (0018-0028, 0030, and including at least one fluorescent compound with illumination ranges outside the visible spectrum (Table 1)), washing of excess dye before image-capturing (0029), and administrations of antibodies associated with GI cancer including CEA (0034-0038). Luiken does not disclose the use of an ingestible imaging capsule; rather focuses on methods involving endoscopes of certain capabilities and other techniques rather than the specific properties of the endoscopes or other imagers used. Attention is then directed to the secondary reference by Alfano et al which discloses an ingestible internal device for wireless capturing and imaging (including storage of images captured) of the GI tract (Col 2 Line 10-65) to enable cancer diagnosis and treatment (Col 3 Line 65- Col 4 Line 59). The methods of Alfano et al include the use of flash illumination capture (Col 6 Line 20-50) and wavelength selection filters in the non-visible light spectrum (claim 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the methods of wireless transmission and endoscopy of Alfano et al with those methods of Luiken for the staining and diagnostic imaging of tissues to enable portable diagnosis of cancer and other diseases with micro-scale technology and onboard storage/transmission.

Claims **40 and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Luiken (US 2001/0055566 A1) in view of Alfano et al (US 6,240,312 B1) as applied to claim 24 above and in further view of Akashi et al (novel Gastric Cancer Associated Mucin Antigen Defined By A3D4). Luiken in view of Alfano et al discloses all that is listed above but fails to disclose the use of an antigenic determinant such as Gastric

Mucin for diagnosis. Attention is then directed to the secondary reference by Akashi et al which discloses such a determinant for the purpose of diagnosing gastric cancer. It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized this Mucin determinant as disclosed by Akashi et al with the methods of Luiken in view of Alfano et al to correctly diagnose cancerous tissues in the GI tract.

Response to Arguments

Applicant's arguments filed 2/2/09 have been fully considered but they are not persuasive. Regarding the argument that neither Luiken ('556) or Alfano ('312) disclose "flashing" illumination to include light and dark periods, in order to obtain a fluorescent image during a dark period, Examiner respectfully disagrees. First, within Alfano, wavelengths of illumination stretch into the non-visible spectrum, and the inclusion of flash lamps does actually imply that "flash" illumination is performed, as flash lamp systems are designed to illuminate an area for a short period of time (capture from a CCD during such a flashing system would inherently measure at least native fluorescence). Regarding the reference to Luiken the plurality of contrast agents utilized includes multiple agents that require illumination in the non-visible spectrum to illicit a fluorescence response (0031-0035, including table 1, and 0021).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML

/BRIAN CASLER/

Supervisory Patent Examiner, Art Unit 3737